

**REMARKS**

Upon entry of the above amendment, claims 13-16 will be pending in this application. Claims 13-16 have been added, and claims 1-4 have been withdrawn, to comply with the Office Action's requirement to elect a species for prosecution. The elected species for prosecution is botulinum toxin type A. New claims 13-16 are fully supported by the specification at, for example, page 29-31 (Example 4), and original claim 1. No new matter is added.

Applicant maintains that the Office Action's requirement to elect a species is improper for at least the reason presented in Applicant's response filed on December 21, 2004. Further, it is Applicant's understanding that an election of species is provisional, and that if the Office finds no prior art that renders the species anticipated or obvious, the search will be extended to non-elected species to the extent necessary to determine patentability of the claim. (See, e.g., M.P.E.P. 803.02). That is, if the Office find no prior art that renders the use of botulinum toxin type A in claim 13 anticipated or obvious, the search will be extended to the use of botulinum toxin types A, B, C, D, E, F and G in claims 1-4 to the extent necessary to determine patentability of these claims.

Applicant also acknowledges the Office Action's rejection of the pending claims for alleged nonstatutory double patenting over U.S. Patent No. 6,767,544 (hereinafter "the 544 patent").<sup>1</sup> As this rejection is provisional in nature, Applicant will address this issue in a subsequent response upon indication of otherwise allowable subject matter in the present application.

**The Claims Are Definite**

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being vague and indefinite. Specifically, the Office Action alleges that the phrase "a

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<sup>1</sup> U.S. Patent No. 6,767,544 cannot be cited to support a rejection under section 103 (a) because the 544 patent is assigned to the same assignee (Allergan) as that of the present application, and the present application has a filing date of January 8, 2004 (which is after November 29, 1999). 35 U.S.C. 103(c).

method for treating improving blood supply through a graft” is not clear. Claim 13 is similar to claim 1. Claim 13 clearly specifies that the invention is directed to a method for improving blood supply through a graft blood vessel. Further, the term “locally administering” is defined by the specification at page 18 to mean “making available”. One of ordinary skill in the art would understand that “making available” a botulinum toxin to the vessel include injection into the lumen of the vessel, application to the surface of the vessel, integration into the tissue of the vessel itself, and diffusion to the vessel from an injection point in nearby muscle.

Thus, claim 13 is definite and clear. Upon the allowance of claim 13, Applicant will amend claim 1 to be similar to claim 13 to overcome the rejection under 35 U.S.C. § 112, second paragraph.

### **The Claims Are Novel**

Claims 1-4 stands rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by the 544 patent “in light” of U.S. Patent No. 5,376,376 (hereinafter “the 376 patent”). Specifically, the Office Action alleges that the 544 patent reports that a botulinum toxin may be administered to a blood vessel in conjunction with a cardiovascular procedure. Further, the Office Action alleges that the term “cardiovascular procedure” recited in the 544 patent includes grafting of blood vessels, since the 376 patent reports that “vein graft is well known in the art as a procedure for reducing a coronary arterial blockage.”<sup>2</sup> Office Action at page 9. Accordingly, the Office Action alleges that the 544 patent teaches that a botulinum toxin may be administered to a graft blood vessel, which is the claimed invention of the present application.

Contrary to the Office Action’s allegation, the 544 patent does not teach that a botulinum toxin may be administered to a graft blood vessel. For example, the claimed invention addresses the problems associated with grafting, e.g., graft stenosis (collapse of

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<sup>2</sup> It appears that the Office Action is using the 376 patent under MPEP §2131.01 to clarify the meaning of the term “cardiovascular procedure” recited in the 544 patent.

the graft). Specification at page 31, lines 20-25. Noticeably, the 544 patent does not discuss the problems associated with grafting. Instead, the 544 patent discusses in detail the administration of a botulinum toxin to a blocked blood vessel that has been cleared by “[a]ny device that may be used to mechanically open a constricted blood vessel, for example, a spring or other expanding device...” See fifth and sixth paragraphs under the Summary section of the 544 patent. Thus, one of ordinary skill in the art would understand that the term “cardiovascular procedure” recited in the 544 does not include grafting procedures of the present invention. Accordingly, the 544 patent cannot anticipate the present claims (1-4 or 13-16) because it does not teach that a botulinum toxin may be administered to a graft blood vessel.

Claims 1-4 stands rejected under 35 U.S.C. § 102 (e) as allegedly being anticipated by U.S. Patent No. 6,579,847 (hereafter “the 847 patent”) “in light” of the 376 patent. Applicant respectfully asserts that the 847 patent cannot anticipate the present claims because it does not teach that a botulinum toxin may be administered to a graft blood vessel. Instead, the 847 patent teaches a balloon dilation catheter coated with botulinum toxin type A and a method for using said catheter to administer the botulinum toxin to an artery wall. Although the 847 patent recites the term “graft”, the “graft” of the 847 patent is not the same as the “graft blood vessel” of the present invention. The graft of the 847 patent is typically formed of Dacron, Gortex and polytetrafluoroethylene materials and is inserted into a damaged vessel for use as a vascular conduit. On the other hand, the graft blood vessel of the present invention is a blood vessel that is taken from one part of the body and grafted onto another part of the body. Thus, the 847 patent cannot anticipate the present claims (1-4 or 13-16) because it does not teach that a botulinum toxin may be administered to a graft blood vessel.

Applicant is unclear as to how the 376 patent is relevant in this rejection. To the extent that the Office intends to use the 376 patent to clarify the meaning of a term used in the 544 patent, Applicant respectfully requests that the Office identify the specific term in the 544 that it seeks to clarify.

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**PATENT**

In view of the foregoing, Applicant submits that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



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